



## **ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OPP-2013-0406; FRL-9400-2]**

### **Pesticides; Repellency Awareness Graphic; Notice of Availability**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA is seeking comment on a repellency awareness graphic for producers of skin-applied insect repellent products to voluntarily place on repellent product labels. This is part of a voluntary, ongoing effort to enhance public health information on, and to improve the clarity of, pesticide product labeling for consumers. Under this effort, producers of skin-applied insect repellent products can seek to use a standardized repellency awareness graphic that will clearly communicate to consumers the estimated number of hours mosquitoes and/or ticks are repelled by a product when used as directed. With this notice, EPA is also seeking comment on a guidance document that describes the recommended criteria and processes for companies to voluntarily request the use of this graphic.

**DATES:** Comments must be received on or before March 6, 2014.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2013-0406, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Rose Kyprianou, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5354; fax number: (703) 305-5884; email address: [kyprianou.rose@epa.gov](mailto:kyprianou.rose@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. What is the Agency's Authority for Taking this Action?*

Sections 2 through 34 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136-136y).

#### *B. Does this Action Apply to Me?*

You may be potentially affected by this action if you manufacture, distribute, sell, or use skin-applied insect repellent products. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers of these products, which includes pesticide and other agricultural chemical manufacturers (NAICS code 325320), as well as other manufacturers in similar industries such as cosmetics (NAICS code 325620).

- Manufacturers who may also be distributors of these products, which includes drug and druggists' merchant wholesalers (NAICS code 424210).

- Retailers of skin-applied insect repellent products (some of which may also be manufacturers), which includes nursery, garden center, and farm supply stores (NAICS code 444220), supermarkets (NAICS code 445110), and sporting goods stores (NAICS code 451110).

- Users of skin-applied insect repellent products, including the general public, as well as landscaping services (NAICS code 561730), sports and recreation institutions (NAICS code 611620), child daycare services (NAICS code 624410), and recreational and vacation camps (NAICS code 721214).

### *C. What Should I Consider as I Prepare My Comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

## **II. Overview**

EPA is preparing to launch a new voluntary effort to enhance public health information and to improve the clarity of pesticide product labeling for consumers. Producers of skin-applied insect repellent products can seek to use a standardized repellency awareness graphic that will clearly communicate to consumers the estimated number of hours mosquitoes and/or ticks are repelled by the product when used as

directed. Participation will be voluntary and has been developed for producers of skin-applied insect repellent products subject to FIFRA registration requirements.

With this announcement, EPA is seeking public comment on the graphic as well as a guidance document that is intended to assist producers in understanding the process for requesting and obtaining approval for the use of the graphic (Ref. 1). Taking into consideration comments provided by the various stakeholders described in the following paragraphs, the guidance identifies the credible information and scientific underpinning that the Agency generally believes is necessary to support the information provided in the repellency awareness graphic. Additionally, the guidance describes for companies and EPA scientists a method for calculating the number of hours for the repellency claim(s) that would be included as part of the repellency awareness graphic. The guidance also describes the process for requesting use of the graphic through applications for new or amended registrations.

EPA believes the approach to determine repellency claim(s) described in the guidance strikes a reasonable balance between rigorous testing design and cost containment. For example, some stakeholder comments suggested a more standardized testing methodology. While this may enhance consistency across tests, it would drive up costs. Since the objective of efficacy testing is to assess and characterize the general performance of each repellent rather than permit rigorous comparisons across products, EPA believes that the approach outlined in the guidance will give reasonably consistent predictions to consumers while ensuring that this program is affordable for companies to implement and flexible enough to allow for future advances in scientific testing methodology.

EPA is making available information on a webpage for consumers (<http://www.epa.gov/pesticides/insect/repellency-awareness.html>) that describes the graphic and how to interpret as well as providing examples of the graphic. In the future, EPA will be launching a new, detailed webpage on insect repellents. The new page will include a list of the products approved by EPA to use the graphic on the product label. Additionally, the new page will provide general information to the public about preventative measures consumers can take to protect themselves and their families from mosquito and tick bites and the potential diseases they may transmit. When launched, the final URL for the program will be <http://www2.epa.gov/insect-repellents>.

### **III. Background**

The repellency awareness graphic was created in response to feedback obtained through focus groups and a national online survey conducted by EPA in 2010 and 2011, respectively (Ref. 2). During the focus groups and survey, consumers indicated that they wanted information about which types of insects are repelled and the number of hours those insects are repelled. Most consumers were aware that mosquitoes and ticks can carry potentially dangerous diseases, and they wanted to know how long they may be protected from those pests. Consumers also responded that they would like this information to be clear, concise, and in large print on product labels.

EPA intends for the repellency awareness graphic to address these consumer needs. The repellency awareness graphic is intended to be displayed prominently on participating products for quick and easy identification by the consumer. Prototypes of this graphic were presented to the consumers participating in the focus groups and national survey, with consumers indicating that they understood the meaning of the

information in the graphic, and that they would be likely to look for this graphic when shopping for skin-applied insect repellents (Ref. 2).

To ensure that a variety of issues and opinions were considered during the development of this effort, EPA requested feedback from several key stakeholder groups. Starting in May 2012, EPA presented the concept, draft guidance document, and draft graphic to OPP's federal advisory committee, the Pesticide Program Dialogue Committee (PPDC), which represents various industry groups, non-governmental organizations, public health professionals, state, local, and tribal governments, and federal agencies (Refs. 3-5). Also beginning in May 2012, EPA asked state regulatory officials participating in the State-FIFRA Issues Research Evaluation Group's Pesticide Operations and Management (SFIREG POM) working committee for their reactions to the idea (Refs. 6-8). Additionally, in March 2013, EPA presented and received independent scientific advice from the Scientific Advisory Panel (SAP) on certain aspects of the effort (Ref. 9). EPA's responses to the SAP's comments relating to the repellency awareness graphic are available in the docket for this notice (Ref. 10).

Throughout the development of this effort, EPA has also collaborated with experts at other federal agencies such as the Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture (USDA), among others. The USDA and CDC have supported EPA's efforts to provide clear and readily visible information about repellent products to consumers. The CDC has indicated that the graphic appears to complement their efforts to promote effective personal protection activities for the prevention of vector-borne diseases such as West Nile virus and Lyme disease (Ref. 11).

#### **IV. Request for Comment**

EPA is providing this opportunity for the public to provide comments and input on the new repellency awareness graphic before it is implemented. Specifically, the Agency requests comment on the following:

- Would addition of the repellency awareness graphic help you choose an insect repellent; would it improve the clarity of label information?
- Is the repellency awareness graphic's design, as shown on the program's webpage, easy to understand?
- What information would be helpful to have on our website about repellency awareness? Is the current information useful and clear to you?

EPA is also seeking comment on a guidance document that describes the recommended criteria and processes for companies to voluntarily request the use of this graphic. While EPA does not intend to formally respond to all comments that are submitted, they will be taken into consideration as EPA finalizes the repellency awareness graphic and guidance. If substantive comments are received, EPA may, if necessary and appropriate, revise aspects of the graphic or the guidance. In addition, EPA may decide in response to any comments, to provide additional helpful information through the website.

## **V. References**

As indicated under **ADDRESSES**, a docket has been established for this notice under docket ID number EPA-HQ-OPP-2013-0406. The following is a listing of the documents that are specifically referenced in this action.

1. U.S. Environmental Protection Agency (EPA). Office of Pesticide Programs (OPP). Repellency Awareness Guidance. For Skin-Applied Insect Repellent Producers.



August 2013. Document ID No.: 730-C-13-001. Docket ID No.: EPA-HQ-OPP-2013-0406.

2. EPA. OPP. Insect Repellent Product Labeling Consumer Survey Report. April 2012. Docket ID No.: EPA-HQ-OPP-2013-0406.

3. EPA. OPP. Pesticide Program Dialogue Committee, May 3-4, 2012 Meeting. <http://www.epa.gov/pesticides/ppdc/2012/may/meeting.html>.

4. EPA. OPP. Pesticide Program Dialogue Committee, November 29-30, 2012 Meeting. <http://www.epa.gov/pesticides/ppdc/2012/november/nov-mtg.html>.

5. EPA. OPP. Pesticide Program Dialogue Committee, July 10-11, 2013 Meeting. <http://www.epa.gov/pesticides/ppdc/2013/july/july2013-mtg.html>.

6. State-FIFRA Issues, Research, and Evaluation Group (SFIREG) Pesticides Operations and Management (POM) Working Committee. Final SFIREG POM Meeting Minutes for May 30-31, 2012. [http://www.aapco.org/meetings/minutes/2012/may30/pom\\_mins\\_05\\_2012.pdf](http://www.aapco.org/meetings/minutes/2012/may30/pom_mins_05_2012.pdf).

7. SFIREG POM Working Committee. Final SFIREG POM Meeting Minutes for September 17-18, 2012. [http://www.aapco.org/meetings/minutes/2012/sep17/pom\\_mins\\_09\\_2012.pdf](http://www.aapco.org/meetings/minutes/2012/sep17/pom_mins_09_2012.pdf).

8. SFIREG POM Working Committee. Final SFIREG POM Meeting Minutes for April 22-23, 2013. [http://www.aapco.org/meetings/minutes/2013/apr22/final\\_pom\\_mins\\_04\\_2013.pdf](http://www.aapco.org/meetings/minutes/2013/apr22/final_pom_mins_04_2013.pdf).

9. EPA. Scientific Advisory Panel (SAP). March 19-21, 2013: Scientific Issues Concerning the Draft Product Performance Data Needs Assessment for Products Claiming Efficacy Against Invertebrate Pests. Background documents available at

Docket ID No.: EPA-HQ-OPP-2012-0574. Additional information available at <http://www.epa.gov/scipoly/sap/meetings/2013/031913meeting.html>.

10. EPA. OPP. EPA Response to Scientific Advisory Panel Comments Related to the Proposed Repellency Awareness Graphic. September 2013. Docket ID No. EPA-HQ-OPP-2013-0406.

11. Kyprianou, Rose. Memorandum on Federal Interagency Consultations During Development of the Repellency Awareness Graphic. September 2013. Docket ID No.: EPA-HQ-OPP-2013-0406.

## **List of Subjects**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests.

Dated: October 28, 2013.

James Jones,  
*Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

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